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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,238	07/03/2001	Lawrence P. Wackett	110.00230102	7517

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EXAMINER

HUTSON, RICHARD G

ART UNIT PAPER NUMBER

1652

DATE MAILED: 08/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/898,238

Applicant(s)

WACKETT ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-10, 17, 18 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-10 and 24-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicants request for reconsideration and withdrawal of the rejections, Paper No. 13, 5/27/2003, is acknowledged. Claims 7-10, 17, 18, and 24-27 are at issue and are present for examination. Applicants' arguments filed on 5/27/2003, Paper No. 13, have been fully considered and are deemed not to be persuasive to overcome the rejections previously applied.

Claims 17 and 18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 7.

Information Disclosure Statement

Applicants submission of the patent application 10/315,490, filed 12/10/2002 by McTavish is acknowledged.

Claim Objections

Claims 26 and 27 are objected to because of the following informalities: Claims 26 and 27 each recite "...80% sequence identity to the amino acid sequence depicted at SEQ ID NO:2.". An amendment such as "...80% sequence identity to the amino acid sequence depicted **by** SEQ ID NO:2." Would be more appropriate.

Appropriate correction is required.

Applicants have not responded to this previous objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9 and 24-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an atrazine chlorohydrolase that comprises an amino acid sequence of SEQ ID NO: 2, does not reasonably provide enablement for any atrazine chlorohydrolase that comprises an amino acid sequence having greater than about 80% sequence identity to SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection is stated in the previous office action as it applies to claims 9 and 24-27.

Applicants traverse this rejection on the basis that it is not necessary to be able to predict exactly which sequences of a protein having 80% identity to SEQ ID NO: 2 (claims 26 and 27) or encoded by a gene having a complement that hybridizes to a DNA that encodes SEQ ID NO: 2 (claims 9, 24 and 25) or biologically active derivatives thereof, will maintain activity, because candidate sequences can be easily screened for atrazine chlorohydrolase activity using the assays described in the specification.

Applicants submit that using the legal analysis employed in *In re Wands*, it is clearly not

necessary for an art worker in the field of molecular genetics to be able to predict in advance which members of a group of candidate compounds or compositions will fall within the claimed class, as long as sufficient guidance exists to enable the art worker to screen the group and identify members of the claimed class and that it is well-settled that a considerable amount of experimentation is permissible if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed. Applicants submit that in the field of molecular genetics, the use of screening methods to identify and select particular molecules of interest from a heterogeneous population created by random laboratory procedures or procedures having a low level of specificity or a low success rate is standard practice, and art workers are highly skilled in the use and evaluation of such screening procedures. Applicants submit what is required under *In re Wands* is sufficient guidance to identify and select the biological molecules that satisfy the limitations of the claims, using screening procedures available to the art or disclosed in the specification. Applicants submit what is not required under *In re Wands* is guidance regarding which regions of a sequence can be modified, the general tolerance of a sequence to modifications, a rational and predictable scheme of modifying any amino acid of a sequence with an expectation of obtaining the desired function and which of the essentially infinite possible choices is likely to be successful.

This is not persuasive because while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan producing variants as claimed by applicants (i.e., having atrazine

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chlorohydrolase activity) requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants have the claimed property. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification. As previously stated the specification does not establish: (A) regions of the protein structure which may be modified without effecting atrazine chlorohydrolase activity; (B) the general tolerance of a atrazine chlorohydrolase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any atrazine chlorohydrolase activity with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Applicants comments regarding what is and what is not required under In re Wands are acknowledged. It is pointed out to applicants that "guidance regarding which regions of a sequence can be modified, the general tolerance of a sequence to modifications, a rational and predictable scheme of modifying any amino acid of a sequence with an expectation of obtaining the desired function and which of the essentially infinite possible choices is likely to be successful" together add up to meet the requirement for "sufficient guidance to identify and select the biological molecules

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that satisfy the limitations of the claims, using screening procedures available to the art or disclosed in the specification". As previously stated and repeated above, applicants specification has not provided such guidance and thus the rejection is maintained.

Applicants comments regarding that one of skill in the art knows that if you start with SEQ ID NO: 2 and make an amino acid substitution here or there, you are likely to end up with a sequence that also has atrazine chlorohydrolase activity and that applicants, by describing SEQ IOD NO: 2, have provided a road map that leads to other atrazine chlorohydrolases are acknowledged, however applicants are reminded that the currently claimed genus encompasses not only an amino acid substitution here or there but the mutation of almost 100 amino acids or a fifth of the total amino acids of the disclosed protein. As discussed above applicants have not provided guidance to enable such a broad genus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 7, 9, 10, and 24-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Mandelbaum et al. (Applied and Environmental Microbiology, Vol 61, No. 4, pages 1451-1457, Apr. 1995, See IDS) as evidenced by DeSouza et al. (Journal of Bacteriology, Vol 178, No. 16, pages 4894-4900, Aug. 1996).

The rejection was stated in the previous office action.

Applicants continue to traverse this rejection on the basis that Mandelbaum et al. do not teach each element of the claim, specifically applicants emphasize that the previous interpretation of "isolated and purified" based on applicants specification, page 8, lines 22-25, as in vitro isolation of a DNA or protein from its natural cellular environment" was incomplete and taken out of context. Applicants submit that the "definition goes on to state "so that it can be sequenced, replicated and/or expressed" and the proteins in the crude cell extract of Mandelbaum et al. are not in a state that they can be sequenced.

Applicants argument is not found persuasive because the referred to complete definition states "As used herein, the terms 'isolated and purified' refer to *in vitro* isolation of a DNA or protein from its natural cellular environment, and from association with other coding regions of the bacterial genome, so that it can be sequenced, replicated and/or expressed". It is the office's interpretation that the crude cell extract of Mandelbaum et al. is encompassed by this reference, as the reference states "so that it can be sequenced, replicated and/or expressed". As this reference does not preclude "further isolation" which may be necessary so that it can be sequenced, replicated and/or expressed, it is the office's interpretation that that isolated and purified protein taught by Mandelbaum et al. is encompassed by this reference and thus anticipates the claims.

Thus claims 7, 9, 10, and 24-27 remain anticipated by Mandelbaum et al. as evidenced by DeSouza et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mandelbaum et al. (Applied and Environmental Microbiology, Vol 61, No. 4, pages 1451-1457, Apr. 1995, See IDS) and Kennedy (See IDS).

The rejection is stated in the previous office action.

Applicants arguments and response mailed on November 26, 2002 are again noted. With respect to applicants comments regarding the dependency of claim 8 on claim 7 are acknowledged, however applicants are reminded that claim 7 is anticipated by Mandelbaum et al. above, and anticipation is the pinnacle of obviousness.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned

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are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Richard G. Hutson", with a long horizontal line extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
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rg
July 31, 2003